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— *Journal of the American Medical Association*, 1997

The first paragraph of Section 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971). Further, a specification "may be enabling even though some experimentation is necessary," *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not "undue experimentation." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is whether the specification "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Further, it is a tenet of patent law that an applicant need not teach what the skilled artisan already knows. Instead, it is preferred that an applicant "omit what is known in the art." *Hybritech Inc. v. Monoclonal Antibodies*, 231 USPQ 81, 94 (Fed. Cir. 1986).

Specifically, the Examiner asserts that each of the claims comprise the limitations that a library of DNA or RNA sequences that are unidentified are transiently expressed in plant host cells from recombinant viral nucleic acids, and that the results of expression of an unidentified nucleic acid sequence in a plant host cell is "correlated" to an uninfected host cell, and a trait identified in either the infected or uninfected host cell. The Examiner further asserts that the claims are broad in scope in that they encompass embodiments wherein bacteriophage or animal viral vectors are used to express the unknown sequences in host cells. The Examiner also asserts that the claims encompass embodiments where infected cells of one type are compared to uninfected cells of another type, and a trait identified, and that the only recombinant viral nucleic acids disclosed by the specification as working examples are ones obtained from plant viruses. The Examiner further asserts that the specification does not clearly define or teach what is meant by "correlating" the changes observed in step d) of the claimed method to an uninfected plant host cell, much less teach how one would do so for plant host cells of differing origin. The Examiner also indicates that the prior art does not appear to compensate for the deficiencies of the instant specification in that it does not appear to address either of these issues. The Examiner concludes that it would take undue, unpredictable experimentation to practice

the claimed methods with 1) viral vectors that were not of plant virus origin, and 2) correlating results of step d) in a plant host cell of one type with an uninfected cell of a differing type. The Examiner indicates that it would be remedial to amend the claims to clearly indicate that 1) the recombinant viral nucleic acids are obtained from a plant virus, and 2) that the correlating step involves plant host cells of the same type.

In response to this rejection, Claim 45 has been amended as suggested by the Examiner to refer to "recombinant plant viral nucleic acids" in steps a) and b).

The Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 45 and 60-70 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area which applicants regard as their invention with a *reasonable* degree of precision and particularity.

1. Specifically, the Examiner asserts that Claim 45 is vague and indefinite in that the metes and bounds of the phrase "... correlating said one former phenotypic or biochemical changes to a host plant that is uninfected ..." are unclear. The Examiner has suggested to clearly indicate the number and nature of steps involved in "correlating" and observed biochemical or phenotypic change in a test plant to the control, uninfected plant. In response to this rejection, in step e) the phrase "correlating said one" has been amended to read "correlating by observation or by biochemical analysis said one." It would be apparent to a person skilled in the art that an observation could be simply looking at a plant and noting a change, and that a biochemical analysis could involve a test for the presence of a new protein by use of a reagent and a color test or by use of an antibody to the new protein.

The Examiner has also suggested to clearly indicate the end result of such "correlation." As indicated in the preamble as amended, the end result of the correlation is to determine the presence of a trait in a plant. In, order to further clarify the end result of the correlation, Claim 45 has been amended to include the phrase "whereby the presence of a trait in a plant is determined." The trait is the result of a change caused by

expression of a foreign gene introduced into the plant by the recombinant plant virus, or recombinant plant viral nucleic acid that encodes the recombinant plant virus. The expression of the foreign gene is set forth in the steps of the claim.

2. The Examiner objects that Claim 45 is vague and indefinite in that the relationship between the biochemical or phenotypic change(s) observed in the test plant of step d) and the identified trait of step f). The Examiner asks if the trait observed f) can be the same as one of the biochemical or phenotypic changes in step d), and indicates that there appears to be significant overlap between what constitutes an observed phenotypic or biochemical change and what constitutes a "trait" in terms of the claimed invention. Secondly, the Examiner asks if there is necessarily a causal relationship between the trait observed in step f) and the changes observed in step d). The Examiner indicates that it would be remedial to amend the claims to clearly indicate the differences, if any, between an observed "change" and an observed "trait," as well as indicating the functional relationship between what is observed in step d) and what is observed in step f). To clarify the claim, step f) has been deleted. As suggested by the Examiner, step e) of Claim 45 has been amended to amend the phrase "phenotypic or biochemical changes" to read "changes in the phenotypic or biochemical traits." This change indicates that the "change" is a change in a "trait."

3. With regard to Claim 45, the Examiner also asserts that the Claim is vague and indefinite in that there is not clear and positive prior antecedent basis for the term "said plant hosts" in step d) of the claims. The Examiner has indicated that it would be remedial to amend the claims to clearly indicate that the term refers to either the infected or uninfected plant host cells, or both. In response to this rejection, Claim 45 has been amended to include the phrase "of the same species" in step e) to clearly indicate that the uninfected and infected host cells are of the same type. To clearly indicate what the term "said host plant" refers to, step d) has been amended to refer to "said infected plant hosts." Finally, step e) has also been amended to refer to a "plant host" rather than a "host plant," for further clarification.


Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date: January 9, 2003

  
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45. (Six Times Amended) A method of determining the presence of a trait in a plant, comprising:

- a) preparing a library of DNA or RNA sequences from a non-plant donor organism, and constructing recombinant plant viral nucleic acids each comprising an unidentified nucleic acid insert obtained from said library in a positive sense orientation;
- b) infecting plant hosts with said recombinant plant viral nucleic acids;
- c) transiently expressing the unidentified nucleic acid inserts in said infected plant hosts;
- d) determining the presence of one or more [phenotypic or biochemical] changes in phenotypic or biochemical traits of [in] said infected plant hosts;
- e) correlating by observation or by biochemical analysis said one or more [phenotypic or biochemical] changes in the phenotypic or biochemical traits to a [host] plant host of the same species that is uninfected [; and
- f) identifying a trait present in said infected or uninfected host plant];

whereby the presence of a trait in a plant is determined.

62. The method according to Claim 45, wherein a positive sense RNA is produced in the cytoplasm of said infected plant host, and said positive sense RNAs results in a reduced or enhanced expression of an endogenous gene in said infected plant host.

63. The method according to Claim 45, wherein a positive sense RNA is produced in the cytoplasm of said [host plant] infected plant host, and said positive sense RNA results in overexpression of a protein in said [host plant] infected plant host.

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Claims as of amendment of January 7, 2003

45. (Six Times Amended) A method of determining the presence of a trait in a plant, comprising:

- a) preparing a library of DNA or RNA sequences from a non-plant donor organism, and constructing recombinant plant viral nucleic acids each comprising an unidentified nucleic acid insert obtained from said library in a positive sense orientation;
- b) infecting plant hosts with said recombinant plant viral nucleic acids;
- c) transiently expressing the unidentified nucleic acid inserts in said infected plant hosts;
- d) determining the presence of one or more changes in phenotypic or biochemical traits of said infected plant hosts;
- e) correlating by observation or by biochemical analysis said one or more changes in the phenotypic or biochemical traits to a plant host of the same species that is uninfected;

whereby the presence of a trait in a plant is determined.

60. The method according to Claim 45, wherein said plant host is *Nicotiana*.

61. The method according to Claim 60, wherein said plant host is *Nicotiana benthamina* or *Nicotiana cleavlandii*.

62. The method according to Claim 45, wherein a positive sense RNA is produced in the cytoplasm of said infected plant host, and said positive sense RNAs results in a reduced or enhanced expression of an endogenous gene in said infected plant host.

63. The method according to Claim 45, wherein a positive sense RNA is produced in the cytoplasm of said infected plant host, and said positive sense RNA results in overexpression of a protein in said infected plant host.

64. The method according to Claim 45, wherein said recombinant viral nucleic acid further comprises a native plant viral subgenomic promoter and a plant viral coat protein coding sequence.

65. The method according to Claim 64, wherein said recombinant viral nucleic acid further comprises a non-native plant viral subgenomic promoter, said native plant viral subgenomic promoter initiates transcription of said plant viral coat protein sequence and said non-native plant viral subgenomic promoter initiates transcription of said nucleic acid sequence.

66. The method according to Claim 45, wherein said recombinant viral nucleic acids are obtained from a plant virus.

67. The method according to Claim 66, wherein said plant virus is a single-stranded plus sense RNA virus.

68. The method according to Claim 67, wherein said plant virus is selected from the group consisting of a potyvirus, a tobamovirus, and a bromovirus..

69. The method according to Claim 68, wherein said tobamovirus is a tobacco mosaic virus.

70. The method according to Claim 68, wherein said potyvirus is a rice necrosis virus.